test(s) will be assigned randomly to a test group in each site where the tests are conducted.

(b)(1) *Prehearing procedures conducted by an Adjudication Officer.* When you file a request for a hearing before an administrative law judge in connection with a claim for benefits based on disability where the question of whether you are under a disability as defined in §§ 416.905 and 416.906 is at issue, the adjudication officer will conduct an interview with you. The interview may take place in person, by telephone, or by videoconference, as the adjudication officer determines is appropriate under the circumstances of your case. If you file a request for an extension of time to request a hearing in accordance with § 416.1433(c), the adjudication officer may develop information on, and may decide where the adjudication officer issues a wholly favorable decision to you that you had good cause for missing the deadline for requesting a hearing. To determine whether you had good cause for missing the deadline, the adjudication officer will use the standards contained in § 416.1411.

(2) *Representation.* The adjudication officer will provide you with information regarding the hearing process, including your right to representation. As may be appropriate, the adjudication officer will provide you with referral sources for representation, and give you copies of necessary documents to facilitate the appointment of a representative. If you have a representative, the adjudication officer will conduct an informal conference with the representative, in person or by telephone, to identify the issues in dispute and prepare proposed written agreements for the approval of the administrative law judge regarding those issues which are not in dispute and those issues proposed for the hearing. If you decide to proceed without representation, the adjudication officer may hold an informal conference with you. If you obtain representation after the adjudication officer has concluded that your case is ready for a hearing, the administrative law judge will return your case to the adjudication officer who will conduct an informal conference with you and your representative.

(3) *Evidence.* You, or your representative, may submit, or may be asked to obtain and submit, additional evidence to the adjudication officer. As the adjudication officer determines is appropriate under the circumstances of your case, the adjudication officer may refer the claim for further medical or vocational evidence.

(4) *Referral for a hearing.* The adjudication officer will refer the claim to the administrative law judge for further proceedings when the development of evidence is complete, and you or your representative agree that a hearing is ready to be held. If you or your representative are unable to agree with the adjudication officer that the development of evidence is complete, the adjudication officer will note your disagreement and refer the claim to the administrative law judge for further proceedings. At this point, the administrative law judge conducts all further hearing proceedings, including scheduling and holding a hearing, (§ 416.1436), considering any additional evidence or arguments submitted (§§ 416.1435, 416.1444, 416.1449, 416.1450), and issuing a decision or dismissal of your request for a hearing, as may be appropriate (§§ 416.1448, 416.1453, 416.1457). In addition, if the administrative law judge determines on or before the date of your hearing that the development of evidence is not complete, the administrative law judge may return the claim to the adjudication officer to complete the development of the evidence and for such other action as necessary.

(c)(1) *Wholly favorable decisions issued by an adjudication officer.* If, after a hearing is requested but before it is held, the adjudication officer decides that the evidence in your case warrants a decision which is wholly favorable to you, the adjudication officer may issue such a decision. For purposes of the tests authorized under this section, the adjudication officer's decision shall be considered to be a decision as defined in § 416.1401. If the adjudication officer issues a decision under this section, it will be in writing and will give the findings of fact and the reasons for the decision. The adjudication officer will evaluate the issues relevant to determining whether or not you are disabled in accordance with the provisions of the Social Security Act, the rules in this part and part 422 of this chapter and applicable Social Security Rulings. For cases in which the adjudication officer issues a decision, he or she may determine your residual functional capacity in the same manner that an administrative law judge is authorized to do so in § 416.946. The adjudication officer may also evaluate the severity of your mental impairments in the same manner that an administrative law judge is authorized to do so under § 416.920a. The adjudication officer's decision will be based on the evidence which is included in the record and, subject to paragraph (c)(2) of this section, will complete the actions that will be taken on your request for hearing. A copy of the decision will be mailed to all parties at their last known address. We will tell you in the notice that the administrative law judge will not hold a hearing unless a party to the hearing requests that the hearing proceed. A request to proceed with the hearing must be made in writing within 30 days after the date the notice of the decision of the adjudication officer is mailed.

(2) *Effect of a decision by an adjudication officer.* A decision by an adjudication officer which is wholly favorable to you under this section, and notification thereof, completes the administrative action on your request for hearing and is binding on all parties to the hearing and not subject to further review, unless—

(i) You or another party requests that the hearing continue, as provided in paragraph (c)(1) of this section;

(ii) The Appeals Council decides to review the decision on its own motion under the authority provided in § 416.1469;

(iii) The decision is revised under the procedures explained in §§ 416.1487 through 416.1489; or

(iv) In a case remanded by a Federal court, the Appeals Council assumes jurisdiction under the procedures in § 416.1484.

(3) *Fee for a representative's services.* The adjudication officer may authorize a fee for your representative's services if the adjudication officer makes a decision on your claim that is wholly favorable to you, and you are represented. The actions of, and any fee authorization made by, the adjudication officer with respect to representation will be made in accordance with the provisions of subpart O of this part.

(d) *Who may be an adjudication officer.* The adjudication officer described in this section may be an employee of the Social Security Administration or a State agency that makes disability determinations for us.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 19

Duty to Report Violations; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulation that gives the responsibility to perform the centralized investigative activities in FDA to another office. The responsibility was recently transferred from the Division of Ethics and Program Integrity, Office of Management and Operations, FDA, to the Office of Internal Affairs, FDA. This action will codify this transfer of functions.

EFFECTIVE DATE: September 13, 1995.

FOR FURTHER INFORMATION CONTACT: Tommy L. Hampton, Office of Internal Affairs (HF–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0243.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 23, 1995 (60 FR 4417), the Department of Health and Human Services published a notice to reflect an organizational change in FDA. The positions assigned to perform the centralized investigative activities located in the Division of Ethics and Program Integrity, Office of Management, Office of Management and Systems, FDA, were transferred to the new Office of Internal Affairs within the Office of the Commissioner.

The new Office of Internal Affairs will serve as an FDA investigative resource to conduct internal FDA investigations and support the Office of Inspector General investigations. Therefore, the agency is amending 21 CFR 19.21 to reflect the organizational change.

List of Subjects in 21 CFR Part 19

Conflict of interests.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 19 is amended as follows:

PART 19—STANDARDS OF CONDUCT AND CONFLICTS OF INTEREST

1. The authority citation for 21 CFR part 19 continues to read as follows:

Authority: Sec. 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371).

2. Section 19.21 is amended in paragraph (a) by removing ''Division of Ethics and Program Integrity, Office of Management and Operations'' and adding in its place ''Office of Internal Affairs, Office of the Commissioner'' ; in paragraph (b) by removing ''Division of Ethics and Program Integrity'' the two times it appears and adding in its place ''Office of Internal Affairs''; and in paragraph (c) by removing ''Division of Ethics and Program Integrity'' and adding in its place ''Office of Internal Affairs''.

Dated: September 5, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–22636 Filed 9–12–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 175

[Docket No. 93F–0276]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethoxylated primary linear alcohols of greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000 for use as components of food packaging adhesives. This action is in response to a petition filed by Petrolite Corp.

DATES: Effective September 13, 1995; written objections and requests for a hearing October 13, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of September 17, 1993 (58 FR 48659), FDA announced that a food additive petition (FAP 3B4390) had been filed by Petrolite Corp., 369 Marshall Ave., St. Louis, MO 63119–1897. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of ethoxylated primary linear alcohols of greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000 for use as components of food packaging adhesives.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, carcinogenic impurities, resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called ''general safety clause'' of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer or Delaney clause (section 409(c)(3)(A) of the act) further provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to the impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive, *Scott* v. *FDA* 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, ethoxylated primary linear alcohols of no greater than 10 percent ethylene oxide by weight having molecular weights of 390 to 7,000, will result in exposure to the additive of no greater than 50 parts per billion (ppb) in the daily diet (Ref. 1).

FDA does not ordinarily consider chronic toxicological testing to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data from acute toxicity studies on the additive. No adverse effects were reported in these studies.

FDA has evaluated the safety of this additive under the general safety clause, considering all available data and using risk assessment procedures to estimate the upper-bound limit of risk presented by the carcinogenic chemicals that may be present as impurities in the additive,